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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,366	04/23/2001	Marie-Christine Etienne	REF/ETIENNE/698CIP	2300

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Richard E. Fichter
BACON & THOMAS, PLLC
Fourth Floor
625 Slaters Lane
Alexandria, VA 22314

EXAMINER	
TRAVERS, RUSSELL S	

ART UNIT	PAPER NUMBER
1617	4

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/839,366	Etienne
Examiner	**Art Unit**
Russell Travers	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-22 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Claims 1-22 are presented for examination.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-22 are rejected under 35 U.S.C. § 101 because the claimed invention, setting forth and incredible utility, lacks patentable utility.

The instant application contains an invention directed to treating various conditions with compounds capable of producing the observed symptomology; wherein these compounds are administered at undetectable levels. Applicants have supplied only anecdotal evidence supporting the therapy herein claims. It is noted that Petit et al (provided in parent) and Labreque et al published studies employing the same manner of therapy herein claimed and found no therapeutic benefit residing therein. The skilled artisan would view a randomized, double-blind, placebo-controlled clinical trial more convincing than antidotal accounts related by Applicants. Absent information, as well grounded as that provided by Examiner cited prior art, the instant claims fail to illustrate the presence of identifiable utility.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines either "active principle, R", or, those compounds that are "a poison, or part of a poison". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "active principle, R", or, those compounds that are "a poison, or part of a poison" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "active principle, R", or, those compounds that are "a poison, or part of a poison", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-11, 13-19 and 20-22 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-11, 13-19 and 20-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11, 13-19 and 20-22 are rendered indefinite by the phrases "active principle, R", or, those compounds that are "a poison, or part of a poison" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining "active principle, R", or, those compounds that are "a poison, or part of a poison" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Labrecque et al Tetau and Applicants' admission on the record, all of record.

Labrecque et al and Tetau teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically divalent metal ions. These medicaments are taught as useful for treating viral diseases. Claims 1-22, and the primary reference, differ as to:

1) the metal ion employed, and

2) the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regimen.

The first deficiency is cured by Tetau teaching employment of divalent metal ions to effect the desired therapeutic goals. The second deficiency is cured by cured by Applicants' admission that the xCH factor effects the therapy in a similar and predictable way. Thus, the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the knowledge to effect the required therapy, and be motivated to apply such therapy, regardless the etiology.

As stated in the instant specification, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients.

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Cazin et al, Besnouin and Applicants' admission on the record, all of record.

Cazin et al and Besnouin teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically arsenic compounds. These medicaments are taught as useful for producing the retention of, or causing excretion of compounds responsible for disease. Claims 8-28, and the primary reference, differ as to:

1) the metal ion employed, and

2) the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regimen.

The first deficiency is cured by information possessed by the skilled artisan and Besnouin teaching the employment of calcium ions to effect the desired therapy. Additionally, Cazin teaches effecting the desired therapeutic goal by employing arsenic, residing in the same chemical period as the claimed antimony. The skilled artisan would have expected compounds residing in the same chemical period to possess therapeutically equivalent effects. The second deficiency is cured by cured by Applicants' admission that the xCH factor effects the therapy in a similar and predictable way. Thus, the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the

knowledge to effect the required therapy, and be motivated to apply such therapy, regardless the etiology.

As stated in the instant specification, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers
Primary Examiner
Art Unit 1617